

**A1052-22 AMNIOCENTESIS 22G QUINCKE- sampler, amniotic fluid (amniocentesis tray)
Smiths Medical ASD, Inc.**

APLICARE POVIDONE-IODINE SOLUTION (povidone-iodine solution) solution
[Aplicare, Inc.]

3/4 Ounce Povidone Iodine Packet

Active Ingredient

Povidone-iodine

Purpose

Antiseptic

Use

Antispetic skin preparation

Warnings

Do not use

-if allergic to iodine.

-in the eyes

For external use only.

Ask a doctor before use if injuries are

-deep or puncture wounds

-serious burns

Stop use and ask a doctor if

-redness, irritation, swelling or pain persists or increases

-infection occurs

Keep out of reach of children

In case of accidental ingestion, seek professional help or consult a poison control center immediately.

Directions

Apply locally as needed.

Inactive Ingredients

citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water

Questions or comments?

1 800 760-3236 (Mon to Fri 8:30 AM-5:00 PM EST)

NDC 52380-0001-3
DIN 02076144

TEAR HERE
POUR



3/4 FLUID OUNCE
POVIDONE-IODINE
SOLUTION

0.75 Fl. oz. (22.5 mL)

STERILE unless opened or damaged.

Drug Facts	
Active ingredient	Purpose
Povidone-iodine USP 10%	Antiseptic
Use antiseptic skin preparation	
Warnings	
Do not use if allergic to iodine	
For external use only	

Reorder No. L-3001

A 7K022 EXP 10-10

TEAR HERE
POUR

Drug Facts (continued)
Warnings
Ask a doctor before use if injuries are ■ deep or puncture wounds ■ serious burns
Stop use and ask a doctor if
■ redness, irritation, swelling or pain persists or increases ■ infection occurs
Do not use in eyes
Avoid pooling beneath patient
Keep out of reach of children. In case of accidental ingestion, seek professional assistance or consult a poison control center immediately.
Directions apply locally as needed
Other information
■ 1% titratable iodine ■ latex free ■ for hospital or professional use only
Inactive ingredients citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water
Questions or comments?
☎ 1-800-760-3236 (Mon to Fri 8:30 AM-5:00 PM EST)



APLICARE, INC.
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0407

Package Label Display Panel

REF A1052-22
AMNIOCENTESIS
22G QUINCKE

PROCEDURAL COMPONENTS:

- 2 Fenestrated Drapes
- 1 Sheet of 3 Adhesive Labels
- 4 Gauze Sponges
- 3 Specimen Tubes (15ml) with Caps
- 1 Quincke Spinal Needle (22G x 3 1/2 in.)
- 2 Plastic Syringes (10ml, Luer Slip)
- 1 Plastic Syringe (6ml, Luer Slip)

PREP COMPONENTS:

- 3 Sponge Applicators
- 1 Povidone-Iodine Solution, 1/4 oz.

WARNING(S):


- A needle stick with a contaminated needle may cause infectious disease.

PRECAUTIONS:

- **Use Aseptic technique.**
- To help prevent needle-stick injuries, needles should not be recapped or purposely bent. If excessive resistance is met during needle insertion, do not force the needle as damage may occur. To help avoid needle breakage, do not attempt to straighten a bent needle; discard it and complete the procedure with a replacement needle.
- After use, place sharps in a suitable sharps container. Dispose of contaminated product in a safe manner according to Centers for Disease Control and Prevention (USA) and Federal/State/Local regulations (EPA, OSHA) and health care facility guidelines or local equivalent.
- Do NOT Resterilize.
- Patient vital signs and response should be monitored during the procedure for any unusual reactions or symptoms.
- To be used only by individuals familiar with amniocentesis procedures. For specific techniques and procedures, refer to standard textbooks.


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PORTEX



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Smiths Medical ASD, Inc.
Keene, NH 03431 USA
Made in USA
www.smiths-medical.com



STERILE EO Rx ONLY

Caution - Do Not Reuse - Latex Free - Do not use if package is damaged - Sterilized using ethylene oxide - **Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

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smiths medical

AMNIOCENTESIS
22G QUINCKE
 Use by: 0000-00
 yyyz-mm
 LUT 000000
REF A1052-22


A1052-22 AMNIOCENTESIS 22G QUINCKE				
sampler, amniotic fluid (amniocentesis tray) kit				
Product Information				
Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:51688-1236	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:51688-1236-2	10 in 1 CASE		
1		1 in 1 PACKAGE, COMBINATION		
Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
Part 1	1 PACKET	22.5 mL		
Part 1 of 1				
APLICARE POVIDONE-IODINE				
povidone-iodine solution				
Product Information				
Item Code (Source)	NDC:52380-0001			

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52380-0001-3	22.5 mL in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	03/01/1984	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	HIO	12/14/2005	

Labeler - Smiths Medical ASD, Inc. (137835299)

Establishment

Name	Address	ID/FEI	Business Operations
Smiths Medical ASD, Inc.		137835299	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Aplicare, Inc.		107255002	manufacture